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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Difenoconazole:** Response to Comments on the Draft Ecological Risk Assessment for Registration Review

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This memorandum communicates the response of the Environmental Fate and Effects Division (EFED) to public comments received on the Draft Ecological Risk Assessment (DRA) for the registration review of the fungicide, difenoconazole (USEPA, 2020; PC code: 128847). The salient comments related to EFED's DRA that were received from Syngenta and the United States of Department of Agriculture (USDA) are addressed in this response.

EFED generally uses an outline format to address public comments (*i.e.*, comment followed by EFED response). Public comments are summarized in *italic* font to capture the essential points. EFED's responses follow. Full comment documents can be found in the Docket (ID: EPA-HQ-OPP-2015-0401)[1]. The DRA will not be updated or addended to address the submitted comments; however, EFED responses may summarize the impact (if any) of the comments to risk characterization.

[1] https://www.regulations.gov/docket/EPA-HQ-OPP-2015-0401/document

EFED Responses to Syngenta Comments:

Syngenta Comment #1:

For difenoconazole use in rice, EPA identified risk concerns for estuarine/marine invertebrates as both acute and chronic RQs exceeded the LOCs. EPA used mysid acute (LC_{50}) and chronic (NOAEC) hazard endpoints and PFAM paddy water concentrations for the 1-day and 21-day EECs in the calculation of the acute and chronic RQs, respectively. Rice is not cultivated in salt/brackish water in the U.S.; the only rice production region that is in close proximity to salt/brackish water in the U.S. is along the Gulf Coast (Texas and southwest Louisiana) and the rice paddies/fields are at least 30 to 40 miles away from salt/brackish waters. Considering rice is grown with freshwater, it is unlikely that estuarine/marine invertebrates would inhabit rice paddies or be exposed to the concentrations as indicated in Tables 8-3 and 8-6 in the risk assessment. Even though the effluent waters from rice paddies could eventually reach salt/brackish water environments that estuarine/marine invertebrates could inhabit, dilution of difenoconazole would have occurred prior to reaching these habitats. In addition, there is a label statement requiring a 14-d holding period of the paddy water before release, which would further reduce the concentration of difenoconazole in receiving waters. Therefore, Syngenta believes that the rice exposure scenario for estuarine/marine invertebrates used in this risk assessment is not realistic and that the Agency should focus on assessing risk to freshwater organisms only for rice uses.

EFED Response #1: EFED acknowledges that some states with rice production like Arkansas and Missouri may not be located near an estuarine/marine environment. However, Kaivila and Hladik (2008) postulated that release of paddy water in summer can potentially reach estuarine/marine environments from riverine inputs of pesticides to the adjacent San Francisco Estuary and watershed. The concentration in rice paddy water is used to estimate exposure to estuarine/marine organisms to be protective of vulnerable areas. Although pesticide concentrations will be lower in many estuarine/marine environments because of mixing, the rate of mixing and tidal dilution (*i.e.*, flux) is highly variable and will not necessarily result in rapid or extensive dilution of the compound in vulnerable estuaries (*i.e.* estuaries with low volume/high residence time) (NRC, 2000; Thomann and Mueller, 1987).

The persistence of difenoconazole in the aquatic environment (DT_{50}s of 301 to 612 days) reduces the effectiveness of the 14-day holding period for release water. The holding period may reduce difenoconazole concentrations in receiving waters due to sorption to soil and sediment but not due to degradation.

The species used in laboratory testing to determine the potential for risk in estuarine/ marine environments is the crustacean Mysid Shrimp [*Americamysis bahia*]. The effects observed on mysids can conservatively be applied toward freshwater crustacean species, for which some species (*e.g.*, crawfish) are commonly reared in conjunction with rice paddies in LA (McClain, 2012). McClain (2012) also indicated that existing rice fields in many states (e.g., AR, MS and TX) are often used in crawfish production. Since difenoconazole is very persistent in aquatic environments (DT_{50}s ranged from 301 to 612 days) and strongly adsorbed (mean Koc of 6112

mL/g) to soil/sediment, identified risk concerns from residual difenoconazole for surrogate crustacean species for both acute and chronic exposures cannot be discounted.

EFED Responses to USDA Comments:

USDA Comment #1: *USDA encourages EPA risk managers to consider available information on the typical rate and number of applications per year in addition to the maximum rate and number of applications on labels. Characterizing modeled risk using typical application rates and numbers of applications will help EPA determine whether non-target organisms are likely to be exposed to difenoconazole.*

For terrestrial exposure, EPA modeled single applications at 0.125 lbs a.i./A for citrus, and 0.0684 lbs a.i./A for pome fruits, which are consistent with agricultural market research data (AMRD, 2015-2019) for average non-seed treatment rates. EPA also considered those rates with four and five applications, respectively. For surveyed states in 2015 through 2019, USDA National Agricultural Statistics Service (NASS) reports an average of 1.5 and 1.8 applications on citrus and pome fruits, respectively (USDA, 2020).

For aquatic exposure, EPA modeled many agricultural use sites in addition to citrus and pome fruits: potato, brassicas, fruiting vegetables, cucurbits, stone fruits, grapes, tree nuts, sugar beet, soybean, and rice. Modeled rates are generally consistent with available data, but non-seed treatment rates for tomatoes, broccoli, and cantaloupes are lower than modeled rates by 20% or more (AMRD, 2020). USDA appreciates that EPA considered labeled requirements for rotation of fungicide modes of action for input parameters for aquatic modeling. However, EPA still modeled two sequential applications and four or five applications per year for most use sites. Where data is available, the average number of applications for surveyed states in 2015 through 2019 is lower in all cases than the modeled number: 1.8 for potato, 1.3 for fruiting vegetables, 1.6 for cucurbits, 1.3 for stone fruits, 1.9 for grapes, and 1.0 for soybean (USDA, 2020). This data indicates that the modeled annual rates frequently exceed real-world use patterns. However, national data may obscure differences that may occur due to differing disease pressure and agricultural practices, thus regional or state data should be considered, where available.

EPA also modeled 0.43 lbs a.i./A for turf, with single and four applications (2 sequential for aquatic exposure), and 0.13 lbs a.i./A for ornamentals, with three applications (2 sequential). National data for turf and ornamentals are not available. Data from the California Department of Pesticide Regulation (CDPR) show an average of 0.22 lbs a.i./A per application in 2015-2017 (49% less than the modeled rate), with an average of <300 lbs per year applied for landscape maintenance, ornamental turf, rights of way, and golf course turf combined (CDPR, 2019).

EFED Response #1: EPA assessed the maximum number of allowable annual applications for all uses (USEPA, 2020) in order to estimate risk for terrestrial and aquatic risks following current label directions. This conservative approach is designed to be protective of aquatic and terrestrial risk concerns for areas where high-end usage occurs. Changing market, pest pressures, and resistance issues may result in higher usage in some areas than reflected in

survey results from the agricultural market research data AMRD (from 2015 to 2020) and the California Department of Agriculture (CDPR) (2019 and 2020) regarding numbers of applications per year and application rates of pounds of difenoconazole per area per year.

EFED acknowledges that fungicide application rates can vary depending on various circumstances such as specific disease severity, environmental conditions, market pressures, and if the treatment is preventive or curative. As USDA noted, it is possible for applicators to legally apply maximum annual application rates for labeled uses using the maximum number of applications per season or year. Other considerations include uncertainties surrounding the actual number of applications by users in different areas and across different seasons, and fungicide resistance management practices.

However, in general, the difference between maximum and typical application rates (if lower than maximum rates) has a linear relationship to corresponding exposure and risk estimates. For example, exposure and risk estimates for a single (hypothetical) application of 1 lb a.i./A are half those for application at 2 lbs a.i./A. The same concept is true for cases with multiple applications when the application interval and timing are the same but only the application rate differs.

USDA Comment #2: *Some of the seeding rates used by EPA to estimate seed treatment application rates are not consistent with current agricultural practices. While differences in seeding rates do not change the number of seeds that must be consumed to trigger an effect, they do change the area that an animal must forage to obtain the number of seeds that could trigger an effect. USDA stands ready to provide updated information on seeding rates.*

EFED Response #2: As noted by USDA, the seeding rate does not influence the number of seeds equivalent to an effect level of concern. For those cases with lower seeding rates than modeled, the foraging area required to reach an effect level of concern could increase.

USDA Comment #3: *Both the Pesticides in Flooded Agriculture Model (PFAM) and Pesticide in Water Calculator (PWC) estimate concentrations due to carry-over of pesticide residues combined with continued applications year after year, which is inconsistent with real-world resistance management practices. In addition, risk exceedance outputs are not likely to be reflective of realistic downstream exposure conditions due to dilution of tailwater after it leaves fields. Estuarine and marine environments particularly are likely to be further away from treated rice paddies thus more prone to dilution.*

Existing labels include extensive environmental hazard and surface water advisory statements (e.g., EPA Reg. No. 100-1262). These include requirements to not apply to water, where surface water is present, or intertidal areas; to not discharge effluent into water bodies without an National Pollutant Discharge Elimination System (NPDES) permit and permission from the relevant authority; and to reduce potential for runoff by avoiding application when rainfall is expected within 48 hours.

Difenoconazole is labeled for use in rice and cranberry. Existing label mitigations specific to those crops in addition to the mitigations above include taking care when applying near non-target aquatic habitats, not releasing irrigation or flood water for at least seven days after the last application, and not applying when weather conditions favor drift to non-target aquatic habitats. As mentioned above, the lack of detections in water monitoring indicate that exposure in aquatic habitats is unlikely.

EFED Response #3: Though both models assume carry-over, and while repeated applications may not be consistent with resistance management recommendations, such recommendations are not mandatory restrictions and there is nothing on the label to prohibit continued application of difenoconazole every year. EFED exposure estimates are intended to represent protective use practices and assumptions.

EFED acknowledges that the concentrations in rice paddy water/cranberry bogs are used to estimate exposure to aquatic organisms to be protective of vulnerable areas. It is uncertain to what extent residues in the water would be diluted after the water leaves the rice paddy/bog as some canals that receive water from the rice paddies/cranberry bogs may have little water in them or the water may be coming from releases from treated paddies/bogs upstream. It is expected that at least in some areas, pesticide concentrations in canals and waters adjacent to the rice paddy and cranberry are very similar to the pesticide concentrations in the rice paddy/cranberry bog.

EFED agrees that estuarine and marine environments particularly are likely to be further away from treated rice paddies thus more prone to dilution. Although pesticide concentrations will be lower in many estuarine/marine environments because of mixing, the rate of mixing and tidal dilution (*i.e.*, flux) is highly variable and will not necessarily result in rapid or extensive dilution of the compound in vulnerable estuaries (*i.e.,* estuaries with low volume/high residence time) (NRC, 2000; Thomann and Mueller, 1987).

EFED agrees that the frequency of difenoconazole detection (0.07%) is low in non-targeted surface water monitoring data. However, it should be noted that monitored concentrations do not likely correspond to model-estimated difenoconazole concentrations because the study design of NWIS (National Water Monitoring System[2]) may not account for all difenoconazole use areas, timing of application, and other factors which may more accurately represent spatially and temporally dependent variables influencing runoff vulnerability. Therefore, uncertainty in the available non-targeted monitoring data make them a weak line of evidence that does not outweigh risk conclusions based on exposure modeling.

[2] https://waterdata.usgs.gov/nwis?

References:

AMRD (2015 -2019) and AMRD (2020) cited in the "USDA Comments on the Draft Human Health and Ecological Risk Assessments for Difenoconazole for Registration Review; EPA-HQ-OPP-2015-0401" document. The cited references are not avaiable in the document.

CDPR. 2019. California Pesticide Information Portal Application, Version 2019.04. https://calpip.cdpr.ca.gov/ Accessed December 29, 2020 by USDA.

Kuivila, K. and M. Hladik. 2008. Understanding the occurrence and transport of current-use pesticides in San Francisco Estuary and watershed. San Francisco Estuary and Watershed cience, Vol. 6, Issue 3: 1-12.

McClain, W.R. 2012. Crawfish Production: Pond construction and water requirements SPAC Publication No. 12. Southern Regional Aquaculture Center, United States Dept of Agriculture.

National Research Council. 2000. *Clean Coastal Waters: Understanding and Reducing the Effects of Nutrient Pollution.* Available at https://www.nap.edu/catalog/9812/clean-coastal-waters-understanding-and-reducing-the-effects-of-nutrient.

Thomann, R. V., & Mueller, J. A. 1987. *Principles of surface water quality modeling and control*: Harper & Row.

USDA. 2020. National Agricultural Statistics Service: Agricultural Chemical Use Program. Quick Stats 2.0 Database. https://quickstats.nass.usda.gov/. Accessed December 29, 2020 by USDA.